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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,687	04/19/2000	MARIAN ELIZABETH LUDGATE	WCM.63	9824

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EXAMINER	
NOLAN, PATRICK J	
ART UNIT	PAPER NUMBER
1644	8

DATE MAILED: 11/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/509,687	Applicant(s) Ludgate et al.
	Examiner Patrick J. Nolan	Art Unit 1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 4, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above, claim(s) *1-35 and 43* is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *36-42* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Part III DETAILED ACTION

1. Claims 1-43 are pending.

2. Applicant's election with traverse of Group IV, claims 36-42 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the combined teachings of Himmler et al., and Ludgate et al., would neither motivate one of skill in the art to make a substitution to Ludgate et al., with the teachings of Himmler et al., absent Applicant's specification and even if said substitution did occur there was no expectation of success in creating Applicant's claimed invention. This is not found persuasive because Himmler specifically teaches why cAMP measurement via CRE elements is preferred over direct cAMP measurement and Himmler et al., also performs said assay with known agonists and antagonists wherein said assay agreed with the reported responses to said compounds. Lastly, cAMP was taught by Ludgate to be produced by CHO-R transfected cells incubated with TSAb, so an expectation of success was taught by the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-35 and 43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

3. Claims 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 36 and 40, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where

the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 36-42 are rejected under 35 U.S.C. § 103 as being unpatentable over Ludgate et al., in view of Himmler et al., both of record

Ludgate et al., teaches a cell stably transfected with a cDNA clone encoding human TSH-R, wherein activation of said receptor is detecting by directly measuring cAMP, so the distinction between TSAb and TBAb can be made (see page R13-R14, in particular).

The claimed invention differs from the prior art teachings by the recitations of transfecting the cells with cDNA promoters containing cAMP response elements which contain the consensus sequence, and cDNA which encodes for the enzyme luciferase, wherein said luciferase levels vary with the amount of induced cAMP levels. However, Himmler et al., teaches a cDNA construct that has a CRE promoter region which contains the consensus sequence TGACGTCA, and a cDNA sequence which encodes for the enzyme luciferase, wherein said luciferase levels vary with the amount of induced cAMP levels. Himmler et al., also teaches that said enzymatic luciferase measurement is far less work intensive than direct cAMP measurement (see abstract, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the direct measurement of cAMP taught by Ludgate for distinguishing between TSAb's and TBAb's for the luciferase enzymatic determination taught by Himmler et al., because the luciferase enzymatic determination is far less work intensive than direct cAMP measurement yet was dose responsive to known receptor agonists and antagonists. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can

normally be reached on Monday through Thursday from 8:00 am to 5:30 pm.

6. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
November 18, 2001